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09/636,243	08/10/2000	Bryan S. Wang	8325-0004	6438

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1627\*

DATE MAILED: 09/25/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/636,243

Applicant(s)

WANG ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group II claims 5 and 6 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and there is no burden on the examiner to examine all of the Groups since Groups I and II are drawn to compositions comprising dimerizing peptides and that Groups I and II are interrelated as both are classified in the same class/subclass. This is not found persuasive because the restriction requirement in the last Office action did not indicate that Group I and Group II are drawn to compositions, as argued. Rather, the restriction requirement clearly indicated that Group I, (claims 1-4) are drawn to a dimerizing peptide and Group II, claims 5-6 are drawn to a zinc finger complex. Although Groups I and II were classified under the same class, as argued however, each Groups was subclassed in different subclasses. Contrary to applicants' further arguments, the search of prior art is inclusive of literatures and foreign patents. Since the literature search is not co-extensive with the Patent search, hence, examination of these two distinct inventions would impose

a great deal of examination of U.S. Patents, foreign patents and publications. Furthermore, the Groups have different patentability determinations under the different statutes.

It is respectfully requested that applicants specifically point out the page number in the restriction requirement that the examiner acknowledged that Groups I and II are related. Attention is directed to page 2 of the Restriction (7/25/02), which recites on the contrary i.e., that these Groups are not related.

Applicants further argue that Group III is not directed to methods of making the products of Group I and II. Rather, these claims are directed to methods of selecting such products. While applicants used the term selecting (which is not one of the statutory subject matter of making, using, compound or composition) however, such selection actually produced or made one of the products. Thus, it is merely a matter of semantics as the same end result is achieved. It is further argued that there is no evidence to support the assertion that other biological or chemical means can be employed for the products. Attention is directed to applicants' own specification at example, page 20, line 24 up to page 21, line 4.

Thus, the process of using cannot be joined with the elected product [and process of making (selecting)], as urged,

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since these are distinct and independent inventions, for reasons discussed above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4 and 7-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

#### ***Status of Claims***

Claims 5-6 are active in the application.

Claims 1-4 and 7-19 are withdrawn from examination.

#### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters Fig. 1, Fig 2 and Figs. 3A-C in the drawings do not correspond to "Fig.1A" at page 29, line 33; "Fig.2B" at page 31, line 16 and Fig. 3, page 32, line 28 of the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicants should further check the specification and drawings to make sure there is a correspondence between the

Figures in the specification and Drawings, since the Drawings were submitted (Preliminary Amendment of 2/5/01) after the as-filed specification containing only two Figures (1 and 2).

#### ***Information Disclosure Statement***

The listing of references in the specification (pages 39-40) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

However, the information disclosure statement (IDS) submitted on 7/9/01 is being considered by the examiner.

#### ***Specification***

The disclosure is objected to because of the following informalities:

A). Sequence ID. No. 2 in the Sequence listing recites the amino acid residues, Asn Asn Gly Lys for the nucleotide sequence 5'NNGK 3'at page 9, line 19 of the specification. This is incorrect. Accordingly, the CRF and paper Sequence Listing are in errors. A new CRF and Sequence Listing are required with the appropriate correction. Applicants are requested to check for

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other errors of this type (to make sure that the amino acid residues are correctly designated as amino acid residues and not nucleic acids or vice versa in the specification and Sequence Listing).

B). The specification is confusing in that it contains two abstracts and two background of the invention. The first abstract appeared as the last page of the as-filed specification i.e., without the inserted applicants' work in the PNAS publication. The BACKGROUND OF THE INVENTION commences at page 1 of the original disclosure. The second abstract and background of the prior art appeared in Example 1. [Example 1 has been incorporated by applicants in the as-filed specification. Cf. with the provisional application of 60/148,422, filed on 8/11/99, which did not include the attached publication]. Working examples provided in the specification should admit an illustration of the invention and need not contain an abstract and/or prior art discussion. The abstract is normally submitted on a separate sheet and not part of the Examples(as done in the original disclosure minus the added publication). Therefore, there seems to be no correspondence between Example 1 and the earlier filed specification (i.e., without the attached PNAS publication). For example, the provisional application and specification (without the attached PNAS publication) appear to

be directed to targeting D-able subsites (as shown in Fig. 1 of the instant specification). The incorporated paper did not make any reference to a D-able subsites rather, a reoptimization of a dimer zinc finger proteins. Explanation and/or correction are required.

C). It contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See e.g., page 7, line 28.

D). The status of the copending applications 09/229,0087 and 09/229,037 at page 3, lines 17-19 have not been supplied.

E). Typographical and grammatical errors: Example of typographical errors are: 5'GCAGAA3'CCC (page 2, line22); "to the a dimerizing peptide" (page 4, line 10); "myb" recited twice at page 17, line 21. Incomplete sentence at page 1, lines 29-30 "DNA recognition subsite".

F). It is not clear as to what the numbers (20-22) at page 36, line 11 stand for. The specification commencing from Example 1 is replete with these parenthetical numbers. It is suggested that applicants check and correct the specification for the presence of these numbers since they are too numerous to mention specifically.



Appropriate corrections are required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The terms "first and second" in claim 5 are relative terms which render the claim indefinite. The terms "first and second" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to how these arbitrary designation are made in reference to. Claim 5 is indefinite as to the term "complex" used as a noun in the

preamble and as a verb "complexed" in the body of the claim. Does it refer to a composition or to a means? The metes and bounds of the term "nonnaturally occurring peptides" are not clearly set forth in the claims.

B). The phraseology "wherein the first and second peptide linkers are first and second copies of the same linker" is confusing as to the reference of copies of the same linker. "The same linker" lacks antecedent basis of support from the base claim 5.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Eisenberg et al (6,453,242).

Eisenberg discloses at col. 10, line 20 up to col. 11, line 10, a zinc finger complex comprising two or more zinc finger proteins comprising a first zinc finger protein having first, second and third component fingers linked to a second zinc finger protein having first, second and third component fingers. Linkage can be accomplished using any of the following peptide linkers. TGEKP (SEQ ID NO:2); GGRRGGGS (SEQ ID NO:4); LRQRDGERP (SEQ ID NO:5); LRQKDGGGSERP (SEQ ID NO:6) ; LRQKD(G.sub.3 S).sub.2 ERP (SEQ ID NO:7). Alternatively, flexible linkers can be rationally designed using computer program capable of modeling both DNA-binding sites and the peptides themselves or by phage display methods. In a farther variation, noncovalent linkage can be achieved by fusing two zinc finger proteins with domains promoting heterodimer formation of the two zinc finger

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proteins. For example, one zinc finger protein can be fused with fos and the other with jun (see Barbas et al., WO 95/119431). Linkage of two zinc finger proteins is advantageous for conferring a unique binding specificity within a mammalian genome. Accordingly, the specific fusion protein of Eisenberg fully meets the broad claimed zinc protein complex.

Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by Choo et al (WO 98/53058).

Choo discloses at page 13, lines 1-11 a zinc finger protein complex comprising of at least two zinc fingers wherein the portions are constructed by joining the required fingers end to end, N-terminus to C-terminus. It is effected by joining together the relevant nucleic acid coding sequences encoding the zinc fingers to produce a composite protein. The protein comprising of the consensus proteins attached to the at least two zinc fingers are linked using linker sequences TGEK or TGEKP wherein P can be deleted from TGEKP or added to TGEK. (page 12, lines 16-20). Also, see page 29, lines 15- 25). Accordingly, the specific zinc protein complex of Choo comprising of zinc finger proteins or the consensus sequence of the zinc finger protein linked by the specific linkers fully meets the broad claimed zinc protein complex.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (PNAS, 3/98).

Kim et al discloses at page 2813, Results section a zinc finger complex comprising a fusion protein of the three finger Zif268 peptide (first fusion protein, as claimed) and an 8-residue peptide linker with Leu at the alpha helical end and Gly added thereto linked to a second peptide linker with Tyr at the first beta sheet with GGGS added therein to form a fusion protein with the shorter linker as 268/NRE and the fusion protein with the longer linker as 268/NRE. See further page 2814, Figure 2, A and B. The two linkers are the modified form of the natural peptide linkers. Accordingly, Kim et al fully meets the instantly claimed zinc finger complex.

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al (PNAS, 1997).

Liu et al discloses at page 5525, col. 1 a zinc finger complex comprising of a two molecules of the three-finger protein with two linkers, TGQKP and TGEKP, modified (i.e., non-naturally occurring, as claimed) by trimming off the C and N terminus of the F3 and F4. At page 5528, col.1 Liu discloses a zinc finger complex comprising, a first protein designated C7-C7, two copies of C7, a phage display selected Zif268 variant were linked together via the linker, TGEKP peptide. A second

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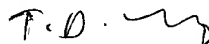
six-finger protein SP1C-C7 combines a designed variant of the three-finger SP1 transcription factor, Sp1C with the finger C7. The C7, Sp1C, C7-C7 and Sp1cC-C7 were expressed as fusions. Accordingly, the specific zinc protein complex of Liu fully meets the broad claimed zinc protein complex.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1627

tdw  
September 19, 2002